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November 29, 2004

Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23<sup>rd</sup> Drive SE  
Bothell, WA 98021-4421

Attn: Michael J. Donovan  
Compliance Officer

This is in response to Seattle District's Warning Letter #04-44. We would like to have this posted on FDA's website.

The inspection took place June 8, 9 and 11, 2004. This is our response to Form 483 to which we responded on July 15, 2004. Our response was not considered in FDA's letter of September 2, 2004.

1. Your HACCP plan does not list one or more critical control points that are necessary for each of the identified food safety hazards. Specifically, the HACCP plan for Dungeness crab products include fresh, cooked, ready-to-eat Dungeness crabmeat in vacuum-sealed 5-lb. metal cans and 1-lb. plastic vacuum packages, does not include a Critical Control Point (CCP) at the distribution step to ensure that vacuum-packaged products are maintained at 38 F or below to control the hazard of *Clostridium botulinum* toxin formation through distribution.

**Reply:** *At the time our HACCP plan for Dungeness crab was written, we were only selling frozen product, not fresh, so there was no need to include this in our plan. We started shipping fresh Dungeness crabmeat in February 2004. We have now added this CCP to our plan. As with the rest of the industry, per revised guideline, we are not shipping any fresh crabmeat in vacuum sealed containers. We are using an 8 oz., 1 lb., and 5-lb. plastic snap top containers with tamper-proof sealing.*

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2. Your HACCP plan lists a critical limit that does not ensure control of one or more hazards. Specifically, the "Cook" CCP's critical limit of "Exposure to temperatures below 165 F" is inadequate to ensure that the cooking process achieved a 6D pathogen reduction.

If, however, you are intending to monitor end product temperature, you need to revise your plan accordingly. Our investigator discussed this approach with you and NFPA's recommendation that adequacy of the cook be established through scientific study.

**Reply:** *We have changed our CCP to read "at least 165 F" and also added that QC checks core temperature every 15 minutes. In 1981, when the continuous cookers were installed, a scientific study was made to determine adequacy of cook to reach EPIPT of at least 165F. We use option #1 of NFPA "Laboratory Memorandum February 2, 2004" as a guide cook @212 F.*

- 2b. Your firm's HACCP plan for cooked Dungeness crab does not list adequate critical limits at the "Cooling" critical control point to control the hazard of pathogen growth and toxin production. FDA recommends a two part critical limit for cooling. Cooked product should be cooled to below 70F within 2 hours of initial handling (i.e., picking) and cooled to 40F within an additional 2 hours. Your cooling process appears to continue throughout the picking and packing process and your product is significantly handled before completely cooled. Therefore, you should monitor the time and temperature of the crabmeat from exit of cooling tank through to final packaging and placed on ice.

**Reply:** *Dungeness crab sections for shaking (picking) come out of the cooker/cooling tank at 73F to 68F. The sections go directly to the shaking table or into iced totes. The temperature of crab sections in totes will come down below 40 F in about 1 1/2 hours. The crabmeat will be in plastic tubs in less than 2 hours from the start of shaking, and placed into totes with ice. The temperature will be approximately 32 F to 34F. Our HACCP plan has been modified to show these CCP's.*

- 2c. In addition, your firm's HACCP plan for fresh shad lists critical limits at the "receiving" critical control point that are not adequate to control histamine. Your plan indicates that you act as a primary processor receiving the shad directly from the harvest vessels and that you collect harvest vessel records. These records should include information associated with method of capture, date/time of landing, air/water temperatures, method of cooling, time cooling began, storage controls onboard the boat and any other factors as needed.

**Reply:** *Our HACCP plan has been modified to show CCP. Received fish are placed in ice within 12 hours and there is no more than 2.5% decomposition on the receiving record.*

- 3a. Your firm did not follow the listed monitoring procedures and frequency of monitoring the time the product is exposed to temperatures above 40 F at the "cooling" critical control point in your HACCP plan for cooked Dungeness crab to control pathogen growth and toxin formation. Our investigator noted that the "Cooling" critical control point is not being monitored to ensure that the time/temperature critical limits are being met. You must adequately implement the monitoring and record keeping procedures for the critical limits in your plan.

**Reply:** *Daily Processing Records have been modified to include temperature control and icing log.*

- 3b. Your firm did not follow your monitoring procedures and frequency as listed in your plan for Dungeness crab at the "Storage Vacuum-Packaged Products" critical control point to control the hazard of pathogen growth and toxin formation. Your plan lists that you will monitor storage temperature continuously. Instead you actually monitor the presence of ice.

**Reply:** *We are no longer packing fresh Dungeness crab in plastic vacuum-packed bags. We have changed to snap top plastic containers, which are iced and inspected with our ice log at least twice daily. Our CCP has been changed to reflect this.*

- 3c. Your firm failed to continuously monitor the exposure temperatures at your "Cook" critical control point. If you choose to monitor a cooking temperature, rather than visually monitoring a rolling boil you should use a continuous time/temperature data recorder.

**Reply:** *Our CCP has been changed to show that we observe the rolling boil and check core temperature every 15 minutes.*

4. To comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the following critical control points to control pathogen growth and toxin formation in your HACCP plan for cooked Dungeness crab and histamine in your HACCP plan for shad.

- a. HACCP plan for cooked Dungeness crab you list an "Icing Log" will be maintained, however your firm failed to maintain this record documenting the monitoring observations for adequacy of ice covering the products.

- b. At the "Storage" critical control point in your HACCP plan for shad you list that a "Storage Record" will be maintained to monitor adequacy of ice, however your firm failed to have a record documenting the adequacy of the ice.

**Reply:** *a. The icing log has been incorporated into the daily process records.*

*b. Icing for shad is included on the bill of lading and the receiving record.*

5. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, the corrective actions listed at the "Cook," "Cooling" and "Storage" critical control points in your plan for cooked Dungeness crab are not adequate because they do not address the cause of the deviations. As part of a HACCP program, FDA expects you to determine how deviation occurred and take steps to prevent its re-occurrence.

**Reply:** *Our HACCP plan has been amended to read "Immediately ice and hold and evaluate and investigate the cause of the deviation."*

6. You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor the following areas of sanitation with sufficient frequency to ensure control as evidenced by.

- a. Prevention of cross-contamination from unsanitary objects to food, food packaging material, and other food contact surfaces, including workers touching unsanitary objects and then handling the cooked crabmeat without sanitizing their hands.
- b. Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants, as evidenced by a worker placing two filled, open cans of crabmeat on a metal stand, next to a bottle of dishwashing liquid.
- c. Condition and cleanliness of food contact surface, as evidenced by
1. Cooked-on greenish residue was present on the surface of the crab cooker/cooler's metal mesh conveyor.
  2. A black substance present on the white UHMW plastic conveyor rotators for the crab cooker/cooler's metal mesh conveyor.

3. A black mold-like substance present on strip curtains at the exit of the water-cooling unit between the crab cooker's exit and the cooler's entrance.
4. A black substance and rust present on the outer and inner surfaces of a vertical PVC water pipe used to fill the crab cooker with water. The pipe was dripping water into the crab-cooking tank throughout processing.
5. A black substance and rust present on outer and inner surfaces of two small horizontal perforated PVC pipes used to continually add water to the crab-cooling tank.
6. Black residue present on the handle and inner surfaces of a small white pitcher used to add water to 5-lb cans of crabmeat as they are filled.
7. The use of packing materials (metal cans) that were not sanitized prior to filling.

d. Exclusion pests from food plant, as evidenced by

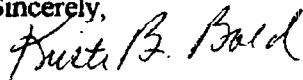
- i. Seven flies noted flying through the crabmeat production area.
- ii. Three small insects, a live weevil-like insect and two dead gnat-like insects, were noted in the bottoms of 5-lb. metal cans on the crabmeat-packing table.

**Reply: a.,b.** *Workers have been advised of proper food handling and hygiene. A safety meeting on food handling and hygiene was conducted with the crew. This type of meeting will be conducted on a regular basis.*

**Reply: c.** *a. Power washing has not been part of the cooker clean-up. It is now being used. Prior to power wash, the cooker is being sprayed with Chlor-Cling and the scale has been removed.*  
*b. Black substance on the conveyor rotators has been removed.*  
*c. Strip curtains have been removed because they are not necessary.*  
*d, e. The black substance and rust has been removed from the PVC pipes.*  
*f. The pitcher has been cleaned.*

**Reply: d.** *Workers check all cans and tubs before filling and have a container of sanitizing water to dip all containers before filling.*

Sincerely,



Kristi B. Bold  
President  
Nelson Crab, Inc.